DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2015

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K143471
Trade/Device Name: VERTEX® Reconstruction System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: December 1, 2014
Received: December 5, 2014

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143471

Device Name
VERTEX® Reconstruction System

Indications for Use *(Describe)*
The VERTEX® Reconstruction System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The VERTEX® Reconstruction System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX® Reconstruction System to the CD HORIZON® Spinal System. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

VERTEX® Reconstruction System
510(k) Summary – K143471
November 2014

Company: Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Lee Grant
Distinguished Regulatory Affairs Advisor

Proprietary Trade Name: VERTEX® Reconstruction System

Regulatory Identification/ Classification: Orthosis, Cervical Pedicle Screw Spinal Fixation
Product Code: NKG
Unclassified, Pre-Amendment

Spinal Interlaminar Fixation Orthosis
Regulation Number: 888.3050
Product Code: KWP
Class II

Description: The subject VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of rods, screws, hooks, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® Cable may be used with this system at the surgeon's discretion.

Indications for Use: The VERTEX® Reconstruction System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The VERTEX® Reconstruction System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited

time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

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Summary of the Technological Characteristics: The subject VERTEX® Reconstruction System has a similar fundamental scientific technology as the predicate AXIS® Fixation System (primary predicate) and is identical to the VERTEX® Reconstruction System (reference device). The subject device utilizes equivalent surgical approaches, implant materials, surgical instruments and sterilization methods as the predicate AXIS® device.

Identification of Legally Marketed Devices: The subject VERTEX® Reconstruction System is substantially equivalent to the predicate cervical spinal system – the AXIS® Fixation System (primary predicate) cleared by the FDA in K062254 (SE 06/16/08). The subject device is also equivalent to the previously cleared VERTEX® devices most recently cleared in K123906 (SE 04/01/2013) and in K123568 (SE 02/25/13) with respect to the implants used to create the constructs utilized for the indications sought. The earlier VERTEX® Reconstruction System clearances are noted for reference purposes only and not as a predicate device for this application.

Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing:
Retrospective clinical data provided in support of this application along with the published clinical outcomes of additional patients treated with the VERTEX® device for the indications sought, demonstrates the subject device is substantially equivalent to the AXIS® Fixation System when used to treat the aforementioned indications. Mechanical testing was also provided to support a substantial equivalence determination of the subject VERTEX® Reconstruction System. Testing consisted of the following:
Unblocked Compression Fatigue and Static Compression Testing of Multi-Axial Screws (MAS) – ASTM F1717
Semi-Blocked Torsion Fatigue and Static Torsion Testing of Occipital Cervical Module with MAS – ASTM F2706

Conclusion: The design features, materials used, indications for use, surgical approach, manufacturing methods and sterilization methods are substantially equivalent to the previously cleared AXIS® Fixation System. The mechanical testing and clinical data provided demonstrate the substantial equivalence of the subject VERTEX® Reconstruction System compared to the predicate AXIS® Fixation System.